No. 20995

In the

United States Court of Appeals For the Ninth Circuit

GLYNN RICHARD DAVIS and
FLORENCE DAVIS, husband and wife,

Appellants,

v.

WYETH LABORATORIES, INC., a New York corporation, and AMERICAN HOME PRODUCTS CORPORATION, a Delaware corporation,

Appellees.

BRIEF OF APPELLEES

Appeal from the United States District Court for the District of Idaho Southern Division

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APPELLEE'S STATEMENT OF THE CASE

Paralytic poliomyelitis is a disease which is caused by what is frequently referred to as virulent polio virus. There are three types of polio virus, namely: Type I, Type II and Type III. There are many individual strains within each of these types of poliomyelitis. The stronger strains are frequently referred to as virulent, and the weaker strains are often called attenuated. A virulent strain is one which has a disease producing capacity. (Tr. 446, lines 16-19) An attenu-

ated strain is a strain of virus which has been manipulated to eliminate disease producing ability. (Tr. 805, lines 2-13) Sabin vaccine was manufactured by appellee with Dr. Albert Sabin's attenuated virus strains. There was no evidence introduced in the case by either party that tended to indicate the existence of virulent virus in the vaccine.

Clinically speaking, human beings acquire polio through the mouth. The virus is usually placed directly in the mouth by the person acquiring the virus. The alimentary tract is that part of the body behind the teeth and ending with the gut. It is commonly believed that the virus multiplies from a few particles to many millions in the throat and gut. When it reaches the gut, it causes an "infection." (Tr. 868, lines 21-25; 869, lines 1-6) The infection is not the disease. One can be infected with polio virus but not become ill or diseased as a result of the infection. (Tr. 602, lines 9-25; 603, lines 1-19) In other words, the infection is not necessarily the disease. One can be infected with polio virus but not become ill with clinical symptoms or disease as the result of the infection.

When the disease results, and this does not happen in all people, clinical symptoms of the disease are manifested. These clinical symptoms usually start with influenza-like ailments, such as headache, stiff neck, fever, diarrhea and the like, and may progress all the way to partial or complete paralysis. (Tr. 866, lines 7-21)

Among knowledgeable members of the medical profession and research scientists, it is not known how the virus is transported from the stomach to the point

where it attacks the motor centers of the body, but it is believed that it is through the blood stream. (Tr. 869, lines 18-25) In any event, the virus is produced in such quantity that it does ultimately get to the spinal column. In the spinal column, the individual virus particles attack the anterior horn cells. The anterior horn cells are the "grey matter" in the spinal column. Destruction of a sufficient number of these cells results in paralysis. (Tr. 603, lines 19-25; 604, lines 1-5)

The polio vaccine involved in this particular case is Sabin oral polio vaccine. The name is derived from Dr. Albert Sabin, who, after many years of research, developed the vaccines. There are three separate types of vaccine, that is to say, Type I, Type II and Type III, each of which is designed to immunize the people who receive it from contracting paralytic poliomyelitis from a corresponding type of polio virus which may be at large in nature. (Exhibit No. 40)

The use of live virus in vaccination for poliomyelitis had been under consideration throughout the world for a number of years, and in the United States it was determined that the Sabin vaccine strains were the ones that should be used. (Tr. 672, lines 9-15) Licensing was handled by the Division of Biologic Standards of the National Institutes of Health, which is a part of the United States Department of Health, Education and Welfare. (Tr. 671, lines 6-14) Ultimately, the United States licensed three manufacturers of the vaccine. Wyeth Laboratories is one of the licensed manufacturers. Wyeth was licensed to sell Type III vaccine on May 17, 1962. (Tr. 676, lines 18-23) Of course, licensing in the United States was preceded by testing in literally millions of people throughout the world. (Tr. 809, lines 19-25; 810, lines 1-15) In the United

States, clinical testing before licensing was performed on between 700,000 and 1,000,000 people. (Tr. 585, line 25; 586, lines 1-5) The Sabin oral vaccine is licensed for sale only as a prescription drug.

The vaccine is usually manufactured in what the production people call "lots." Each lot of the vaccine is manufactured under the standards devised by the Division of Biologic Standards, which are extremely complex and technical. These particular standards are in evidence as defendant's Exhibit 57. (Tr. 673, lines 2-6) The virus used in the vaccines, without regard to who manufactures it, all comes from a common source. When Wyeth Laboratories determined that it would attempt to manufacture the vaccine, they obtained from Dr. Sabin a so-called "seed" virus, and this original seed is still maintained and is still the parent of each lot of separate vaccine manufactured by the Wyeth Laboratories. (Tr. 621, lines 5-10) The virus is grown in minced monkey kidney tissue, which has been placed in a nutrient media. (Tr. 620, lines 6-12) After the individual crop of virus has been completely grown, it is harvested and then used in the preparation of the vaccine.

The individual lot is run through a number of tests in the manufacturing laboratory, including a neurovirulence test in monkeys. All of these tests are extremely difficult and quite sophisticated. The tests are generally summarized on page 621 through line 7 of page 626. These tests, in addition to acting as a standard against which the safety of the vaccine can be measured when used by humans, also are for the purpose of establishing an identity of the vaccine virus to the original seed virus obtained by Sabin. This is done through the neurovirulence test in monkeys. In

that test, the vaccine, in various dilutions, is injected directly into the brains of monkeys in the thalmus and intra-spinally in the lumbar enlargement of the spinal cord, which is the most sensitive part of the cord. The monkeys are observed for a number of days and from observations and later dissection of the sacrificed animals, testing scientists are able to determine whether or not the vaccine has met the standards prescribed by the United States Government. This test is described on page 627, at line 3 through page 628, line 16.

Following manufacture and satisfactory testing within the laboratories, the vaccine involved in this case was then sent to the Division of Biologic Standards of the United States where it was again subjected to rigorous testing, including a neurovirulence test in monkeys. (Tr. 648, lines 17-25; 649, lines 1-25; 723, lines 2-25; 724, lines 1-21) If the United States Government is satisfied with the results of the test, individual authorization for the release of the lot is granted to the manufacturing laboratory. All of these things were, of course, done in connection with the vaccine which appellant claims he consumed, which was part of Wyeth's Lot 35. The vaccine in Lot 35 was released by the Government for sale on January 31, 1963. (Tr. 694, lines 7-12) At the time of its release, it conformed to the standards established by the Government. (Tr. 650, lines 1-8, Exhibit 78)

The vaccine involved in this particular case was packaged in small bottles, each of which held 100 doses of the vaccine. (Tr. 654, lines 1-7) This particular vaccine was sold by Mr. James Franklin, a salesman for Wyeth Laboratories, to the Southeastern Idaho Medical Association at Idaho Falls, Idaho, and was in-

voiced to the association by the appellees. (Tr. 111, lines 12-16, Exhibit 32) Each vial of the vaccine sold contained a package insert explaining the nature and characteristics of the vaccine, giving directions for its use and setting forth all of the conditions and circumstances that had been reported about the vaccine to the time of the sale which might have an adverse effect on the desired and anticipated result from the use of the vaccine. (Exhibit 40) The medical society in east Idaho was the entity which determined that it would be wise to use this vaccine in West Yellowstone, Montana, since West Yellowstone has no doctors or advanced medical facilities and most of the people in that territory are patients of doctors in Southeast Idaho. (Tr. 108, lines 13-25; 110, lines 1-11) As a result, some of the vaccine was shipped to Mr. Robert Brower, a druggist at West Yellowstone, Montana. (Tr. 171, lines 15-24) The package insert explaining the drug was in the vaccine sent to Mr. Brower. Mr. Brower used the vaccine and appellant alleges that he consumed some of it, for which he paid the sum of 25 cents, which Mr. Brower took from him. Mr. Brower later forwarded the fund that he had collected to Mr. Del Simpson, an accountant for the medical society at Idaho Falls, Idaho. (Tr. 170, lines 14-15) On about April 14, 1963, appellant began to manifest symptoms of illness and was hospitalized at Ashton Memorial Hospital in Ashton, Idaho. He was then transferred to the L.D.S. Hospital at Idaho Falls, Idaho, and later to the Elk's Rehabilitation Home in Boise, Idaho. Thereafter, he went to the Veterans Administration Hospital at Boise, Idaho. (Exhibits 31, 2, 3 and 4)

The use of Sabin oral vaccine in the State of Idaho was not a decision that was reached by the appellees.

On March 31, 1962, Dr. Terrell O. Carver, Administrator of the Idaho Department of Health, and Dr. Robert E. Staley, then president of the Idaho State Medical Association, issued a press release which went to public health personnel, physicians and members of the press. In that release, they noted that a meeting had been held with officers of the State Medical Association and several component medical societies in the State of Idaho, together with representatives of the Department of Health, and the United States Public Health Service. Through the press release, all of these people had recommended that mass immunization clinics for the vaccination of the populace be held. (Tr. 757, lines 3-25; 759, line 1, Exhibit No. 46)

One of the people attending this meeting was Dr. John Mather, Director of the Division of Preventive Medicine for the State of Idaho. (Tr. 873, lines 15-17) This doctor identified the recommendation of the United States Public Health Service, Exhibit 56, and recommended the use of the mass immunization clinics, even though he recognized a possible attendant risk. (Tr. 897, lines 16-25; 898, lines 1-2) Another man attending the March, 1962, meeting was Dr. John Casper, who served as county physician in Bonneville County, Idaho, and as State Health Officer for the same area. (Tr. 756, lines 2-4) Dr. Casper concurred in the recommendation for the use of Sabin vaccine and in the joint press release from the State of Idaho, the Medical Society and the United States Public Health Service. (Tr. 758, lines 18-24, Exhibit 46)

Dr. Casper, not the appellees, was the man who introduced the idea of establishing mass immunization clinics in Eastern Idaho. He presented the concept to

the president of the Idaho Falls Medical Society and to the Public Health Committe of the Society, then to the membership of the Society. (Tr. 759, lines 9-24) The Public Health Committe of the Society consisted of Dr. Casper and five other physicians. (Tr. 760, lines 3-8) This committee was charged with the responsibility of selecting which manufacturer should provide the vaccine. There were three manufacturing laboratories, Lederle, Pfizer and the appellee, Wyeth Laboratories. (Tr. 761, lines 3-9) Of course, all of the drugs are essentially the same; they are Sabin oral vaccine, and Dr. Casper pointed out that the only real difference was in the method of administration. (Tr. 762, lines 16-25; 763, lines 1-2) Based on the method of administration, the committee selected the Wyeth product. (Tr. 763, lines 3-6)

These mass immunization clinics were originally scheduled in the fall of 1962. (Tr. 764, lines 4-6) It was also decided by the Public Health Committee that they would coordinate the mass immunization clinics throughout Eastern Idaho, including the upper Snake River Valley, the Idaho Falls area, and Pocatello, Idaho. (Tr. 768, lines 1-6) In order to coordinate these various groups, a meeting was held at Blackfoot, Idaho, attended by the principal doctors involved and the head of an advertising agency, Jim Tyme. (Tr. 765, lines 7-23)

The decision to use the vaccine in West Yellowstone, Montana was made by Dr. A. A. Krueger, a practicing physician in Ashton, Idaho. He requested that the vaccine be sent to West Yellowstone, Montana. His request was directed to James Franklin, Wyeth's salesman. (Tr. 106, lines 8-25; 108, lines 13-18; 110, lines

2-11) Dr. Krueger asked the pharmacist in West Yellowstone, Montana, Mr. Robert Brower, to administer the vaccine, because he "was the only one remotely related to the medical profession in the area." The reason for sending the vaccine from Idaho into West Yellowstone, Montana, was based on the fact that there are no doctors in West Yellowstone, and patients there used Ashton, Idaho, medical facilities. (Tr. 106, lines 15-24; 777, line 14)

Meanwhile, the Surgeon General of the United States of America had created a Special Advisory Committee on the use of oral polio vaccines. In September of 1962, the Surgeon General's committee had made a press release, together with an official release to medical people advising them that there might be a risk in the taking of the Sabin oral vaccine. This release is in evidence as Exhibit 9. The appellee's salesman, James Franklin, read about that release in a Pocatello newspaper. (Tr. 94, lines 18-23) The newspaper release was the first information obtained by anyone in the Wyeth organization. He notified the Medical Society at Idaho Falls about the release, through Dr. John Casper. (Tr. 95, lines 1-9) Following that notification, a meeting of the Public Health Committe was called by Dr. Casper to discuss the Surgeon General's report. (Tr. 771, lines 23-25) As a result of that meeting, Dr. Casper and several other of the doctors placed a telephone call to Dr. Luther Terry, the Surgeon General, in Washington, D. C., and talked to one of his assistants. (Tr. 772, lines 11-21) Following the telephone call, they continued the planning for the program, but delayed their clinics. (Tr. 772, lines 24-25; 773, lines 1-2) The delay in the program and the reason for it was released by Dr. Casper and the committee in a

newspaper article which is in evidence as Exhibit 79. (Tr. 773, lines 12-24)

Another report of the Surgeon General's committee was issued on December 18, 1962. This is in evidence as Exhibit No. 10. Dr. John Casper was familiar with the report and had seen it prior to the clinics. (Tr. 774, lines 15-25) Knowing the risk, the committee of the Medical Society decided to go ahead with the program in the spring of 1963. (Tr. 775, lines 2-8) The dates for the clinics were established by the Public Health Committee. (Tr. 778, lines 16-18)

Most of the mechanics of local immunization and the operation of the clinics was set up under the direction and control of Dr. John Casper in his capacity of Public Health Service Doctor. His office stored the vaccine, and he was present when it was unloaded and repackaged for shipment to other points. (Tr. 779, lines 1-18) Advertising was handled by the society and their paid advertising representative, James Tyme. (Tr. 764, lines 21-25; through 765, line 6) The organization had the clinics set up in various schools and public buildings. (Tr. 764, lines 7-11) The advertising was placed in the form of flyers and distributed in grocery stores and similar public establishments.

The monies received from the clinics were turned over to Mr. Del Simpson, an accountant in Idaho Falls, Idaho. (Tr. 225, lines 24-25) Mr. Simpson had been requested by Dr. Casper, acting for a group of doctors, to act as accountant for the clinics. (Tr. 256, lines 16-25) The funds were deposited in the Bank of Commerce, Idaho Falls, Idaho, as a special account and withdrawals required the signature of Del Simpson

and Dr. Reid Fife. (Tr. 257, lines 13-21) From these funds, the medical society's bill for the vaccine, Exhibit 32, was paid in full. At the conclusion of all fund payments, the balance of the account was turned over to the various medical societies in Idaho. (Tr. 263, lines 8-10)

The entire program had a marked degree of success, since approximately 90% of the population was vaccinated. (Tr. 780, lines 23-25; 781, lines 1-3)

GENERAL ARGUMENT

Due to the complexity of this case, appellees' argument has been divided in two sections. This section generally argues and highlights factual matters, while legal theories are stated in a separate section of the argument.

Care in Manufacturing and Testing

One of the most interesting aspects of appellant's brief is the assumption that Wyeth's Sabin oral vaccine was a defective product. Appellant has not cited wherein the product was defective, nor pointed out those portions of the transcript which establish a defect in the product; yet the cases cited by appellant all involve products which were determined to be defective.

The trial of this cause required some two weeks, and a great many of the witnesses were called for the purpose of showing the extreme care used in manufacturing the product and thereafter testing it before it was placed on the market.

Dr. Alan Bernstein described this entire manufacturing process from the time monkeys were selected and observed before kidney material was used in the process to the point where the vaccine was ultimately tested, cartoned and stored for use.

Dr. John H. Brown was the director of appellees' Marietta, Pennsylvania, facility where the manufacturing was handled. He carefully described the extremely complex method used in testing the vaccine by the appellees before a portion of the material was submitted to the United States Government for further testing. These tests are all summarized in a document which the experts call "protocols." These protocols are in evidence as Exhibit 44.

Thereafter, the material was sent to the Division of Biologic Standards of the National Institutes of Health, which is a part of the United States Department of Health, Education and Welfare. Dr. Roderick Murray, the director of that division, testified and described the manner in which the product was originally licensed for sale in the United States, before individual laboratories started producing vaccine. Thereafter, he described the method used to test the product within the Division of Biologic Standards. His testimony further showed that this specific lot of vaccine was released by the Department before sale to the public.

Dr. Ruth Kirschstein, an assistant to Dr. Roderick Murray, testified concerning detail of some of the tests she ran on this particular Lot 35 manufactured by Wyeth Laboratories. This included the extremely complex neurovirulence test in monkeys, which cannot

be easily described. Those test results are summarized and appear in Exhibit No. 78.

In addition to all of the physical testing on the material itself, field testing had also taken place. Millions of people were served with Sabin vaccine throughout the world prior to the time it was used in the United States. Wyeth Laboratories, through the director of its clinical testing facilities, Dr. M. Z. Bierly, again field tested the vaccine before use within the United States.

At no point during the course of the trial was it ever suggested that the appellees were negligent in manufacturing the vaccine, testing it, or handling it in storage. Under such circumstances, it is difficult to perceive how the appellants can claim that the vaccine was defective in any respect whatever.

The Role of the United States Government

One of the unusual aspects of this case is the tremendous role the United States Government played in the manufacturing of Sabin oral polio vaccines. The Surgeon General of the United States of America had established an Advisory Committee on oral polio vaccines. Within this Advisory Committee there existed a Technical Committee which assisted the Division of Biologic Standards in establishing standards of testing vaccine material before it was to be released to the population as a whole. Dr. Roderick Murray, previously mentioned herein, was the director of that division and a member of the Surgeon General's committee. He identified the standards used by the division which are in evidence as Exhibit No. 57. Through many pages of testimony, Dr. Murray explained the methods of setting the standards, the method of exam-

ining protocols and retesting vaccine within his division. The result of the division's work with regard to Lot 35 is best summarized on page 696 of the transcript, lines 1 through 5:

> "Q. With respect to the release then of this particular lot, a determination was made by the division that this lot met the standards of the division for purity, potency and safety?
>
> "A. That is correct, yes."

In addition to actual physical testing of the product, the division maintains a degre of surveillance over advertising. All labels and package inserts are submitted to the Division of Biologic Standards before they are used by a particular company. (Tr. 707, lines 5-22) Another member of the Technical Committee established by the Surgeon General was Dr. David Bodian. He serves as Director of the Department of Anatomy at Johns Hopkins University, School of Medicine, and is considered one of the world's leading authorities on the pathogenesis of poliomyelitis. The greater portion of his life has been devoted to research in the poliomyelitis field. (Tr. 867 lines 7-10) He pointed out in his testimony that the Technical Committee was the one that developed the standards under which the vaccine was produced and tested. (Tr. 837, lines 2-10) The larger part of the Surgeon General's committee, of which Bodian was also a member, was called together to review the results of the first use of licensed oral poliomyelitis vaccine in the field. (Tr. 837, lines 13-15)

The review of the use of the vaccine in the field was handled primarily under the auspices of the Epidemiology Branch of the Communicable Disease Center,

United States Public Health Service. This branch is headed by Dr. Alexander D. Langmuir, who also testified. The CDC authors the Polio Surveillance Unit Reports, a number of which are in evidence as exhibits in this case. (Exhibits 10, 58, 59, 61, 63, 62, 65, 64, 68, and 74, 76 and 77 are examples) It was this larger committee which statistically evaluated the risk involved in the administration of the oral polio vaccines. Several other members of the committee testified at the trial. These included Dr. John P. Fox and Dr. Ernest A. Ager.

The role of the United States in the manufacturing, testing, distribution and use of the drug was manifest throughout the trial. The United States originally licensed the drug for production, and then released each production lot after testing. Government agencies examined the labels and package circulars, as well as the boxes containing the drug. A Government committee established the standards for manufacturing and testing. The Public Health Service urged the mass immunization clinics, which is evident from Exhibits 46 and 56. Following the administration of the vaccine, the United States then monitored the results through the Communicable Disease Center to determine if there was a relationship between the vaccine and subsequent polio cases. This was done, of course, on a statistical basis.

Evaluating the Risk

Appellant complains that no one advised him as to the risk involved in taking Type III Sabin oral polio vaccine. He insists that the appellees had a duty to warn him of this risk, and failed to do so.

Initially, it was not known that there was any risk in the taking of Type III vaccine. The risk was first evaluated in the Surgeon General's Report of September 22, 1962, which contains a number of press releases and is in evidence as Exhibit 9. The risk was re-evaluated in a December 18, 1962, report of the Surgeon General's committee, in evidence as Exhibit 10. Final evaluation of the risk was made in the 1964 Surgeon General's report, in evidence as Exhibit 11. Table 9 therein establishes the risk at .40 cases per million population. In the age group above 40, the risk is at .42 cases per million of population. Dr. David Bodian describes the risk as "minimal" for Type III vaccine.

"Q. I believe that in the article which you have written in the book that you described earlier (referring to the witness's article in *Viral and Rickettsel Infections of Man*, chapter 18) you stated that the risk is minimal for Type III, as well as Type I and Type II?

"A. That is correct. May I just add that this is with reference to the type of risk encountered with other immunizing agents. When you say minimal, you have to have something in mind and we there refer to the history and knowledge of the kind of risk that people have to undergo, have to expect and be led to expect when they develop medical procedures.

"Q. So, in terms of the other procedures such as smallpox vaccination, surgical procedures or any of the things that people do for a medical or health reason—this risk would be mini-

mal. Actually, when you mention it, the risk from the taking of the live polio vaccine is minimal when compared, for example to the taking of smallpox vaccine; is it not?

"A. Yes."

(Tr. 859, lines 5-24)

Furthermore, the risk in the vaccine has never been established with any particular case, and the Surgeon General's committee carefully pointed out that there is no laboratory test which provides a definitive answer that can establish that an individual case was or was not caused by the vaccine.

"It should be emphasized that the committee does not consider that an individual case can be proved to be caused by the vaccine and no laboratory test has thus far provided a definite answer."

(Page 4, Exhibit 10)

The report further indicated that no specific lots of vaccine or vaccines of a particular manufacturer could be associated with cases.

"That there was no apparent association of cases with specific lots of vaccine and vaccines produced by a particular manufacturer."

(Page 4, Exhibit 10)

Of course, the association of poliomyelitis in a particular individual with the vaccine is strictly an epidemological conclusion. The science of epidemiology

Dr. John Casper testified that the Public Health Committee of the Idaho Falls Medical Society carefully considered the risk, and was aware of it.

> "We had to make that decision as a member of the Public Health Committee; would it be better to drop the whole program and perhaps take the risk of an epidemic of polio in the community, and particularly of the Type III in that Type III was being a more significant source of polio in that the Salk vaccine was . . . seemed to be more effective for type I and Type II, but did not produce an immunity to Type III. And that seemed to be more of a problem, and that was the decision we had to make . . . Was it better to drop the program and have a risk that the community is going to be subjected to a polio epidemic. We had not had any polio for quite some time, and it is a common belief that polio epidemics occur in a cyclical effect, every seven years. You have a problem every few years, and we had not had any polio for quite some time, and the decision was made that the benefit far outweighed the disadvantages of the quoted statistics of one in a million."
>
> (Tr. 787, lines 3-20)

The risk was also the subject of much medical literature. It was discussed in the Journal of the American Medical Association for October 15, 1962, in evidence as Exhibit 49, summarized briefly on page 32 of the Journal of the American Medical Association for January 12, 1963, in evidence as Exhibit 51, and again discussed in the JAMA on January 26, 1963, in evidence as Exhibit No. 42. The problem was also discussed in the local newspapers and appeared in the Idaho Falls Post Register in an article in evidence as

Exhibit No. 52. Termination of the Idaho Falls clinics scheduled for the fall of 1962 was discussed in a newspaper article on September 18, 1962, in evidence as Exhibit No. 79.

Finally, Dr. M. Z. Bierly prepared the package insert contained in every carton of vaccine, and that package insert carried the summation of the risk attendant in the vaccine. The full text of the package insert with regard to the warning appears on page 597, line 8, through page 599, line 6, of the transcript.

Of course, the Public Health Committee of the Idaho Falls Medical Society had real reason to consider the risk, since appellee's salesman, James Franklin, specifically advised them that a risk might be involved in the feeding of the vaccine. Dr. Casper acknowledged receipt of a copy of the Surgeon General's report in 1962. (Tr. 768, lines 23-24; 769, lines 1-14) He also recalled placing a telephone call to an Assistant Surgeon General of the United States with his committee listening in on the call. (Tr. 776, lines 8-21) This meeting resulted from the fact that James Franklin had read an article in the newspaper about the risk while he was in Pocatello, Idaho, and so advised the committee. (Tr. 94, lines 18-25; 95, lines 1-15)

It is difficult to perceive how deep appellant wished to have the warning run, since the entire medical profession seemed to be aware of the risk. This is, after all, a prescription drug and certainly the duty to warn was fully met when all of the physicians were advised of the medical literature available on attendant risk, if any there was.

Finally, in evaluating the risk it is almost impossible to determine when a medical risk becomes un-

reasonable. There is certainly some problem in the use of any medical procedure, including the use of vaccines for other medicines. Dr. Bodian recognized this as noted above. Appellant's witness, Dr. Riemert Ravenholt, recognized it:

"Q. Is there a medical risk involved in the use of smallpox vaccine?

"A. There is some risk, yes.

"Q. That would approximate in the one in a million people will probably die?

"A. This is under more careful measurement at the present time, but this is not too far from the mean.

"Q. And two hundred eighty-five in a million will be seriously ill?

"A. That is the definition of seriously ill.

(Tr. 490, lines 11-21)

Dr. Fox looked at the medical risk in this fashion:

"A. Very much so. There are very few completely safe therapeutic or preventative agents, and I actually cannot off hand think of another vaccine, except Type II or Type I, or all polio, that has a smaller risk associated with its use, especially toward someone with its consequences."

Appellant charges that the risk in taking Type III vaccine is grossly misleading. Appellant's brief, page 7. Appellant's witness, Dr. Reimert Ravenholt, is cited as the authority establishing the true risk. It is evident from his testimony that Type III poliomyelitis was on the rise in the United States. During the course of

cross-examination, Dr. Ravenholt was handed Exhibit No. 63, later offered and accepted into evidence, and from that exhibit he testified as follows:

"Q. Doctor, you have before you what is in evidence as defendant's Exhibit No. 63. Will you examine page 5 of the table? Isn't it true that in 1961, that 44% of all isolations of polio virus from patients afflicted with poliomyelitis were of Type III?

"A. This is true for the cases reported here. I do not know how many were paralytic.

"Q. It does not show how many were paralytic; for the northwestern states, this would show in Idaho 3 of 6 isolations in the state were Type III?

"A. Correct.

"Q. And in Oregon, 3 of 5 isolations were Type III?

"A. Correct.

"Q. And in Washington, 10 of 12 isolations were Type III?

"A. Correct."

Furthermore, it was more than evident from Dr. Ravenholt's testimony on cross-examination that the attack rate of poliomyelitis was 4/10th of a case per million for the population given the vaccine. (Tr. 488, lines 11-15) Plaintiff's Exhibit No. 11, and specifically Table 9 thereof, establishes that in persons taking the vaccine in the age group of 40 or over, the attack rate was .42% per million, or 2/100ths of a per cent higher than the population as a whole. Dr. Ravenholt acknowledged this fact. (Tr. 489, lines 1-8).

STRICT LIABILITY

A. COURT'S REFUSAL TO INSTRUCT ON STRICT LIABILITY WAS NOT ERROR

Appellant's first specification of error is without merit. Appellant urges that the court erred in refusing to instruct the jury on the doctrine of strict liability (or, as appellant terms it, "absolute" liability), and in taking the cause from the jury. In passing on the question of implied warranty, the jury has necessarily decided the question of strict liability against appellant. This is for the reason that the doctrine of strict liability does not truly impose "absolute" liability, and is applicable only when the product is ". . . in a defective condition unreasonably dangerous to the user or consumer. . . ." Restatement (Second) Torts § 402A (1965)) The jury was instructed on implied warranty to the effect that the product must have been "reasonably fit and reasonably safe for consumption." (Instruction No. 14, Tr. 940) The jury determined the product *was* reasonably fit and reasonably safe for consumption. This is tantamount to a finding that the product was not "defective." Therefore, a basic fact necessary for the imposition of liability upon the appellee—a defective product—under either a negligence theory, a breach of warranty theory, or a strict liability theory, has already been determined by the jury against appellant, and the parties hereto are bound by such determination.

In *Hurley v. Beech Aircraft Corp.*, 355 F.2d 517 (7th Cir., 1966) the plaintiff-appellant complained of the dismissal by the trial court of a breach-of-warranty

count. However, by its findings of fact holding against plaintiff after trial of a negligence count, it was held that the trial court had necessarily found that the assembled product was free of the one defect about which complaint was made. The effect of such finding was that there could not have been a breach of warranty. Accordingly, the appellate court held the dismissal by the trial court of the breach-of-warranty count was not reversible error, stating in part as follows:

> "Plaintiffs do not dispute the law of collateral estoppel by judgment; but they do try to escape its effect by arguing that the only findings essential in the negligence case would have been findings to the effect that the defendant assembled, inspected and tested the plane as a prudent manufacturer would have done under the circumstances and exercised ordinary care in the process. This argument ignores the fact that to find no defect in the aircraft is to find no basis for the charge of negligence in the manufacture of the aircraft and is thus merely a negative way of stating that the manufacturer was not negligent.
>
> "(2) In light of the foregoing, we conclude that the question of fact, whether the aircraft was defective, was common to both counts of the complaint. Without such defect, there could have been no negligence as charged in count II and no breach of implied warranty as charged in count I. The determination of that fact was critical to the trial court's determination of count II and was not beyond the issues. Under the doctrine of collateral estoppel by judgment, plaintiffs are now barred from proceeding under count I. . . ."

Another case to the same effect is *Lewis v. Baker*, 413 P.2d 400, a 1966 Oregon case. This case involved the drug, MER/29, wherein the complaint alleged both negligence and breach of warranty. At the trial of the cause, the jury heard plaintiff's evidence on the issue of negligence. An issue was made whether or not the manufacturer had disclosed fully to the Food and Drug Administration of the United States Government all known and relevant information concerning the safety of the drug. The case was submitted to the jury on the theory of negligence, the trial judge withdrawing from the jury's consideration the issue of implied warranty. On appeal, the withdrawal of the implied warranty theory from the jury was urged as error. The court held that the jury's finding was tantamount to a finding that the product was reasonably safe. The court stated:

"(3-6) From the evidence in the record, the jury could have found either way upon the question whether the manufacturer had disclosed fully to the Food and Drug Administration all known and relevant information concerning the safety of the drug. The verdict for the defendant was, in effect, a finding that there was no willful or negligent mislabeling. We hold that upon such facts a drug, properly tested, labeled with appropriate warnings, approved by the Food and Drug Administration, and marketed properly under federal regulation, is, as a matter of law, a reasonably safe product. Accordingly, a person claiming to have suffered adverse effects from using such a drug, unless he can prove an impurity or an inadequacy in labeling, may not recover against the seller for breach of warranty.

"(7) From what has been said about the immunity of a prescription-drug manufacturer from warranty liability when federal agency approval has been properly obtained and the drug is marketed with all required safeguards, it follows that upon proof of fraud or culpable non-disclosure in the obtaining or retention of such federal approval there should be no such immunity.

"While outright fraud was not alleged in the case below, and is disclaimed in the plaintiff's reply brief, the jury did hear the plaintiff's evidence on an issue of negligence in failing to give adequate warnings concerning possible harmful side effects of the drug. In a somewhat analogous situation, where the trier of fact found that a product alleged to have been negligently assembled was free of the one defect complained of, there could not have been a breach of warranty. Accordingly, the withdrawal by the trial court of the breach-of-warranty issue was held not a reversible error. *Hurley v. Beech Aircraft Corporation*, 355 F.2d 517 (7th Cir. 1966).

"(8) Thus, in the case at bar, where the jury necessarily found, in effect, that there was no culpable nondisclosure in the labeling of the drug, even though the jury passed upon that question under a negligence instruction rather than under a warranty instruction, there would appear to be no reversible error in the withdrawal of the warranty issue. No useful purpose could be served by sending the case back for another trial on the issue of culpable nondisclosure. To the extent that the issue was tendered by the pleadings, it was submitted and settled during the trial below. See *United States v. Moser*, 266 U. S. 236, 242, 43 S. Ct. 66, 67, 69 L.Ed. 262 (1924).

either doctrine, is that the product in question must be one that is not reasonably fit for the ordinary purposes for which such articles are sold and used. The jury in this case found that the product *was* reasonably fit for ordinary purposes for which it was sold and used. Therefore, appellant's argument that the doctrine of strict liability should have been presented to the jury by an instruction is moot, because the jury has already found against him on this point and he is bound thereby.

B. STRICT LIABILITY INAPPLICABLE TO "UNAVOIDABLY UNSAFE PRODUCTS"

Even if the effect of the jury's finding is ignored, there is cogent reason for the court's not giving a separate instruction on strict liability. The vaccine in question, even if it were held to involve some risk in the absolute sense, would still fall within the Restatement definition of an "unavoidably unsafe product." In Restatement, (Second) Torts §, 402A (1965), paragraph k, unavoidably unsafe products are defined as follows:

> "k. *Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a pro-

duct, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk."

Thus, even under the Restatement of Torts rule, which can hardly be said to be in favor of or promulgated by manufacturers of products, respondent would have no strict lability.

C. MODIFIED IMPLIED WARRANTY *IS* STRICT LIABILITY

Additional justification — if any is needed — for the trial court's action is that in instructing on implied warranty (shorn of its ordinary common law and sales act qualifications) the trial court did, in effect, impose strict liability. The strict liability aimed at by the Restatement of Torts is hardly more than the classic

doctrine of implied warranty stripped of its traditional qualifications.

As stated in *Green v. Clark Equipment Co.*, 327 F. Supp. 427. at 429, (D. C. Ind. 1965):

> "Without attempting an exhaustive explanation, it may fairly be said that the liability which this section (Restatement (Second) Torts, § 402A) would impose is hardly more than what exists under implied warranty when stripped of the contract doctrines of privity, disclaimer, requirements of notice of defect, and limitation through inconsistencies with express warranties."

Appellant could hardly have hoped for a more liberal instruction by the trial court in this case. Appellant, in effect, did receive an instruction on strict liability. The case cited by Appellant in support of its specification of error No. 1, *Greenman v. Yuba Power Products, Inc.*, 377 P.2d 897 (Cal. 1963), also recognizes this. All the court decided in that case was that courts should simply recognize that strict liability for defective products is being imposed and should straightway declare that they are imposing strict liability in lieu of engaging in the vain circumlocution involved in protesting that recovery is based on implied warranty without its ordinary contract qualifications. *Greenman* is merely a plea for forthrightness; it effects no novel substantive change. The quotation adopted by appellant in his brief shows this when the court is quoted as saying: ". . . Although in these cases strict liability has usually been based on the theory of warranty . . ." Appellant in this case received the advantages of strict liability. His only complaint is that the court labeled it implied warranty rather than strict liability.

D. INAPPROPRIATENESS OF "DEFECTIVE" PRODUCT CASES

Finally, the cases relied upon by appellant are inappropriate factually. The jury has already determined that a "defective" product was not involved. Appellant's cited cases all deal with "defective" products. Appellant's *Greenman v. Yuba Power Products* case requires a "defect" before the doctrine comes into play. Appellant's *Marrow v. Caloric Appliance Corp.* holds the defendant as a warrantor of the fitness and reasonable safety of a gas cooking range. This case merely abolishes the traditional requirement of privity of contract, and actually requires less than the trial court has already granted appellant in the instant case. Appellant's *Goldberg* case is also a case which does nothing more than abandon the privity requirement. Appellant's *Santor* case, as pointed out in the excerpt from 2 Frumer and Friedman, Products Liability, hereinbefore quoted, specifically limited its holding to "defective" products.

The case of *Wright v. Massey Harris, Inc.*, also cited by appellant, is yet another case involving a product specifically determined to have been "defective."

The Idaho Supreme Court, in the *Bethlahmy* case, cited and quoted at page 14 of appellant's brief, quite explicitly pointed out in its opinion that a defective product (a residence) was involved. In its opinion, which imposed an implied warranty of fitness upon sellers of new houses, the court stated (415 P.2d, at 702):

". . . Plaintiffs commenced this action for rescission and restitution, mainly on the ground of defendants'

failure to disclose the *defective* condition of the house. The presence of the unsealed irrigation ditch through the lot and beneath the garage, coupled with the fact that the basement was not of waterproof construction, constituted major *defects*, known to defendants, and unknown to plaintiffs, and not discoverable upon reasonable inspection. Failure to disclose such *defects* would support a finding of fraud. Obde v. Schlemeyer, 56 Wash. 2d 449, 353 P.2d 672 (1960) . . ." (emphasis added)

In further discussing the requirement that such homes need be only "reasonably" fit, the court stated (Op. Cit. *supra* at 711):

". . . The implied warranty of fitness does not impose upon the builder an obligation to deliver a perfect house. No house is built without defects, and defects susceptible of remedy ordinarily would not warrant rescission. But major defects which render the house unfit for habitation, and which are not readily remediable, entitle the buyer to rescission and restitution. The builder-vendor's legitimate interests are protected by the rule which casts the burden upon the purchaser to establish the facts which give rise to the implied warranty of fitness, and its breach. See Schipper v. Levitt & Sons, Inc., supra . . ."

Thus, appellant has failed to cite this court any authority which should govern or be persuasive in the case at bar, since the product in question herein was properly determined by the jury to have no defect.

In fact, there is respectable authority to the effect that appellant in this case was not even entitled to an

instruction on implied warranty. In 3 Frumer and Friedman, *Products Liability*, §33.02 (2) (d) the following appears:

> "Recent authority, however, indicates that there is no breach of warranty if an unadulterated drug, properly tested, labeled with appropriate warnings, and approved by the Food and Drug Administration, causes an adverse reaction. It has also been held that such a drug is not unreasonably dangerous within the rule of strict liability in tort." (Citing *Cornish v. Sterling Drug, Inc.*, No. 14,713-3 (WD Mo. May 13, 1965) (CCH *Products Liability Reports*, Sec. 5415); *Cochran v. Brooke*, 490 P.2d 904 (Ore. 1966); *Lewis v. Baker*, 413 P.2d 400 (Ore. 1966); *Cudmore v. Richardson-Merrell, Inc.*, 398 S. W.2d 640 (Tex. Civ. App. 1965)

Factually, there is no question but that the drug in the present case was properly tested, labeled and approved by the Government.

Therefore, it appears that appellant, not satisfied with having received a warranty instruction which was not justified by the record in this case, is now attempting to convince this court that the jury could or would have found a legally cognizable defect in the product if it had been presented with that same question under the different label of "strict liability."

DUTY TO WARN—NEGLIGENCE

Appellant urges as error, in separate specifications numbered 3 and 4 in his brief, the failure of the court to instruct on negligence and the failure to instruct on duty to warn. In the factual situation involved in this case, the specifications are one and the same. For, if

there is any negligence, it must be in that the respondent failed to warn. The evidence is without conflict that the drug was pure and uncontaminated, and the jury so found. When the drug left the lab it is clear that there was no negligence, in that the product was pure and uncontaminated. Any negligence must have arisen after the drug left the lab. The only possible act for which the manufacturer might be held accountable would be in its failure to warn. Therefore, the negligence—duty to warn argument is one and the same. That this is so is evidenced by the following quote:

> "Since the record shows without conflict that the drug was pure and uncontaminated in manufacture, negligence, if any, would have to be predicated upon evidence that the company failed adequately to warn of the dangers of its use."
>
> *Love v. Wolf*, 38 Cal. 183, 192 (Cal. 1964)

The warning required is only to the doctors or the medical profession, and not the ultimate consumer. *Love v. Wolf, supra; Stottlemire v. Cawood*, 213 F. Supp. 897 (D. C. Cir. 1963). There can be no factual contention that such warning was not given to the doctors involved. Mr. Franklin went well out of his way and far exceeded the task enjoined upon a reasonable man to warn. Immediately upon learning of the possible consequences from use of the drug, Mr. Franklin called a meeting of the Southeastern Idaho Medical Association, Public Health Committee, and told them of the Surgeon General's finding. Not content to rest there, Mr. Franklin caused a telephone call to be placed to Luther Terry, Surgeon General of the United States, to request advice. The doctors so advised were thus in possession of the same knowledge which Wyeth Lab-

oratories had. Certainly a defendant manufacturer cannot be expected to reveal something which neither he, nor anyone else, knows. The trial court made no error in taking this issue from the jury. Indeed, in the context of the record before this court, if the trial court had instructed on negligence based on a failure to warn and the verdict was against the manufacturer, the manufacturer would have more than ample cause to vigorously complain in this appellate court. This duty to warn was carried out so thoroughly, efficiently and convincingly that no two reasonable persons would disagree that the duty in this regard was discharged.

This duty to warn giving rise to negligence is not an absolute duty. As stated by the author of the annotation in 76 ALR 2d, page 16:

> ". . . The rule as to when a manufacturer or seller must warn (or, stated differently, when he will be held negligent if he fails to warn) is this: A manufacturer or seller of a product which, to his actual or constructive knowledge, involves danger to users has a duty to give warning of such danger. . . ."

The author cites almost three pages of authority to substantiate this proposition. As stated, the manufacturer must have actual or constructive knowledge of the danger. When appellee manufacturer in this case obtained this actual knowledge he did in fact warn those whom it was his duty to warn. This duty to warn only arose when appellee acquired knowledge of the dangerous condition. There was no duty to warn prior to the Surgeon General's report because the product was not in fact dangerous. As stated in 76 ALR 2d at page 21:

"Since a manufacturer or seller is obliged to warn of product connected dangers of which he has actual or constructive knowledge, it follows as a matter of elementary logic that no duty to warn arises with respect to a product which is not in fact dangerous."

It can be argued with respectable authority that when the Surgeon General's report brought to light that there was less than one in a million chance of anyone contacting poliomyelitis from the drug in question, that no duty to warn thereby arose. In other words, where there is only a remote possibility of danger from the use of the product in question there is no duty to warn at all. *Bish v. Employers Liability Assurance Corp.*, 236 F.2d 62 (5th Cir. Ct. App. La. 1956); *Katz v. Arundel-Brooks Concrete Corp.*, 220 Md. 200, 151 A.2d 731 (1959); *Pontife v. Sears Roebuck & Co.*, 226 F.2d 909 (4th Cir. Ct. App. Va., 1955); *Merrill v. Beauty Views Corp.*, 235 F.2d 893 (10th Cir. 1956); *McGee v. Wyeth Laboratories*, 29 Cal. App. 2d 322 (1963).

Appellant states on page 27 of his brief that this is a novel case and that no court in the land has passed on the issue of duty to warn in the situation where a prescription drug is sold but there is "no patient-physician relationship." This, of course, assumes that at least the legal equivalent of such relationship was not present in this case to such an extent as to sufficiently establish effectiveness of the warning to the only group of persons who could properly evaluate any risk involved, which appellee submits is not true. In any event, it is the position of appellee that even if the well-established rules concerning prescription drugs are complete ignored, the principle that a warning to the im-

mediate purchaser is sufficient. As stated in 76 ALR 2d, at page 25:

> "Assuming that there may be recovery, regardless of lack of privity of contract, on the basis of a manufacturer's negligence in failing to warn his immediate vendee, there can be no recovery on such basis by one other than the immediate vendee where adequate warning was given the immediate vendee."

Illustrative of this principle is the case of *Travis v. Rochester Bridge Co.*, 18 Ind. 79, 122 N.E. 1 (1919), when the court held that a manufacturer of an article who sells it knowing of a defect has a duty to give notice to the purchaser and is liable to the purchaser or any other person injured as a consequence of the defect. However, if he notifies the purchaser, his liability is at an end, and any liability for injury to third persons rests upon the purchaser.

The principle is again illustrated in *Foster v. Ford Motor Co.*, 139 Wash. 341, 246 Pac. 945, 48 ALR 934 (1926). This action involved a plaintiff-employee's suing the manufacturer of a tractor when the tractor tipped over on the employee while he was trying to extricate it after it became stuck in the mud. The court reversed the judgment in the plaintiff's favor on the basis that the manufacturer couldn't be held liable on failure to give notice because he gave notice to the employee's employer. An English court, in *Holmes v. Ashford*, 2 All E.R. 76 (CA) (1950), held the manufacturer of "Inecto" hair dye was not liable to a woman injured when the dye was applied to her hair by a beauty parlor operator whom the manufacturer had warned.

It would therefore seem that just as the interposition of a physician in the sale of a prescription drug between the manufacturer and the user is in effect held to be a supervening cause, the same principle is applicable where adequate warning has been given to a non-physician vendee who may be reasonably expected to recognize any risk involved by reason of the warning given. And even if this court were to hold that a legally sufficient equivalent of the technical physician-patient relationship was not present herein, it is submitted that the vendees of this vaccine, the Eastern Idaho Medical Society, were in fact the proper parties to receive and adequately evaluate the warning given by appellee, since general information and warning of any risk involved had been effectively disseminated to the general public prior to the time appellant claims to have contracted this disease.

Still another reason that the trial court herein properly did not give an instruction on the duty to warn is the fact that there was no proof that any claimed failure to warn caused the appellant to take the vaccine in question.

The necessity for proof of such a causal relationship is stated by the author of the above mentioned annotation, 76 ALR 2d at page 66, as follows:

> "Assuming that in a negligence action against the manufacturer or seller of a product alleged to have caused injury, it is shown that the defendant failed to comply with his duty to give adequate warning regarding the product, it does not necessarily follow that the defendant is liable for the injury. One of the hurdles (present in all negligence litigation) standing between proof of a negligent failure to

warn and ultimate recovery is the necessity of proof of a proximity causal relationship between the negligence and the injury."

It is the position of appellee that it cannot be stated, based upon the record before this court, that "but for the absence of an effective warning" appellant would not have taken the vaccine. In fact, common sense and knowledge of the mainsprings of human conduct would unavoidably bring one to the opposite conclusion. Simply stated, that proposition is this: a man has less than a one in a million chance of contracting the dreaded disease of polio if he takes the vaccine. If he does not take the vaccine, his chances of contracting polio are abundantly increased. There is no evidence whatsoever in this case that even if plaintiff-appellant had been given a specific and detailed warning he would have refused to take the vaccine. Common sense indicates prudence would move a reasonable man to take such a minimal risk as is involved herein.

Still another of the great variety of possible justifications which the trial court had for denying the request to instruct on failure to warn as negligence is that the respondent in the instant case is, at best, in an analogous situation to those with allergies or peculiar susceptibility to a particular product. Witness the case of *Bonowski v. Revlon*, 100 N.W. 2d 5 (Iowa, 1959), a case involving sun tan lotion. The court at page 89 stated:

"The testimony is that one person (plaintiff) in five million was allergic to the combination of the sun tan and sun shine. . . . Neither the seller nor the manufacturer is liable for breach of warranty or for

negligence where an isolated buyer is allergic or unusually susceptible to the product."

The case of *Bish v. Employers Liability Assurance Corp.*, 236 F.2d 62 (5th Cir. La., 1956), is also illustrative. This case involved a home permanent containing ammonium thioglycolite. The court in that case stated at page 62:

> "In the absence of either a danger or knowledge of a danger of the use of a product, or where there might be only a *remote possibility* of danger, failure to warn is not negligence. Nor is a warning required as to product where an injury results from the sensitivity of allergy of a person in the use of a product which would be innocuous to normal people." (Emphasis added)

In *Kaenpefe v. Lehn & Fink Product Corp.*, 249 N.Y.S. 2d 840, (App. Div. 1964), the court held that there is no duty to warn "the unknown few who constitute a mere microscopic fraction of potential users who may suffer allergic reaction not common to the ordinary or normal person." To hold the manufacturer responsible for warning a minuscule segment of the population would be in no wise agreeable to common sense or justice.

INAPPLICABILITY OF RES IPSA LOQUITUR

Appellant urges the applicability of the doctrine of *res ipsa loquitur* in his Specification No. 2 with an apparent disregard of what is pertinent. There is an affirmative and unqualified showing of the absence of negligence in the record before this court. If, as in this case, the appellant's own proof shows that there was

no negligence and that all proper means were taken to insure the purity of the drug, there certainly is no need or justification for the doctrine of *res ipsa loquitur*. *Res ipsa loquitur* is an evidentiary doctrine that upon proof of a certain set of circumstances a jury is permitted to infer negligence in the absence of some rebuttal. The rebuttal in this case was furnished by appellant's own evidence, as well as appellee's evidence. The evidence in this case so completely refutes any negligence on the part of appellee that claims to the contrary are in utter defiance of the evidence of record.

Appellant cites *Berry v. American Cynamid Co.*, 341 F.2d 14 (6th Cir. 1965). The appellate court remanded the matter to the district court with instructions to take evidence on the experience in the use of Sabin oral vaccine and to redetermine the validity of the second count of the complaint in the light of such evidence. However, in the instant case, evidence *was* taken on the experience in the use of Sabin oral vaccine. This evidence showed that only four in ten million users of the Sabin oral vaccine contracted poliomyelitis. Such a microscopic statistical number by itself destroys the doctrine of *res ipsa loquitur*. If 9,999,996 out of ten million users fail to contract polio this is certainly evidence of a complete and utter absence of negligence. Certainly one could infer any number of things other than negligence in the face of such staggering statistics. One could infer that the particular person who was the one in two and one-half million had a special susceptibility which was unknown to medical science. One could infer that the drug was not even the cause of the disease. One could infer that poliomyelitis was previously contracted. One could infer that the drug itself was totally ineffective and did

not act to cause (or to prevent) poliomyelitis in the four in ten million. The list of other permissible inferences from the mere circumstances adduced by appellant in this case is practically inexhaustible.

The jury has already determined that the vaccine was reasonably fit and reasonably safe for the purpose for which it was intended. Therefore, at the time the vaccine was distributed the presence of any possible previous negligence had been negated by such determination. It was incumbent upon the appellant to prove that some act subsequent to manufacture was negligent. We have already seen that the only possible act upon which appellant could ground negligence was in the failure to warn. There, however, was no duty to warn for a great variety of reasons. (This is in addition to the uncontroverted evidence that there was in fact warning by appellee.) This precludes any claim of negligence. Appellant is attempting to till arid and infertile soil in urging the applicability of an evidence doctrine which is irrelevant under the facts of this case. It is also interesting to note that in relying on the doctrine of *res ipsa loquitur* to set up a permissible inference of negligence, the appellant is not capable of pointing out any tangible object in the exclusive control of appellee. There was no negligence in the preparation of the product (the jury found the product reasonably fit and reasonably safe). Therefore, an act of negligence must have come *after* the manufacture. After the manufacture and sale of the drug, appellee had no exclusive control of it. Up to and after the manufacture, there was no negligence according to the jury's finding. One cannot infer that the failure to warn caused the poliomyelitis. A "defective"

drug must have caused it. But, as we have seen, there was no "defective" drug.

Additionally, there are any number of drug cases holding the doctrine of *res ipsa loquitur* inapplicable. One of these cases is *Webb v. Sandoz Chemical Works*, 85 Ga. App. 405, 69 S.E.2d 689 (1952). This action was against a manufacturing chemist, the producer of a drug known as "Cafergone", for injuries sustained as a consequence of taking the drug. It appeared that the drug was prescribed by plaintiff's physician for alleviation of plaintiff's migraine headaches; that plaintiff took the drug in accordance with the physician's directions; that the physician's directions complied with directions which defendant gave for the taking of the drug; and that as a result of the use of the drug the plaintiff suffered a permanent impairment of vision. Upholding a nonsuit, the court said that the *res ipsa loquitur* doctrine was inapplicable and the evidence demanded a finding that no negligence on defendant's part was shown. It was pointed out by the court that there was proof that it was good medical practice to prescribe "Cafergone", notwithstanding the fact that sometimes bad results might follow where persons had individual sensitivity to drugs not discoverable in the exercise of ordinary care. In *Henderson v. National Drug Co.*, 343 Pa. 601, 23 A.2d 743 (1942), the court held, without even bothering to discuss the point, that *res ipsa loquitur* was not applicable to the facts presented. The facts were that the action was brought against a drug manufacturer for an abscess which developed on plaintiff's back where the doctor injected him with a liver extract manufactured by the defendant. The doctor testified that the abscess was due to an irritant in the liver extract, and that other patients

injected with the same product also developed abscesses. The court, in reversing, held the evidence insufficient to establish that the presence of irritants in the injection given plaintiff was due to the negligence of defendant. The inference that defendant failed to use due care in the preparation of the liver extract was said not to be so compelling as to exclude the equally reasonable inference that the plaintiff's physician did not use due care in its administration. In that case there were, in fact, similar abscesses which developed in other people. Yet, the court held that there was no negligence. Now, of course, for appellant in the present case to prevail, the doctrine of *res ipsa loquitur* which he advances must be advanced against negligence in preparation of the Sabin vaccine. This has been decided against appellant, because the jury determined that the product when it came out of the laboratory was a perfectly good product. Another case holding the *res ipsa loquitur* rule inapplicable was *Tuscany v. U. S. Standard Product Co.*, 243 S.W.2d 207 (Tex. Civ. App. 1951). This was a case wherein the plaintiff sought damages for injury to his wife who injected herself with a drug known as estrogenic hormones. The act of negligence pointed to by the plaintiff on the part of the defendant manufacturer was negligence in the preparation of the product. The court affirmed the judgment in defendant's favor, pointing out that plaintiff could offer no evidence of any positive act of negligence on defendant's part, and that although the accident and injury to the plaintiff's wife were proved, as were surrounding circumstances from which it might have been reasonably inferred that the injury was a result of some negligence (either on the part of the defendant or on the part of the plaintiff's wife), this was not enough under the *res ipsa loquitur*

rule to impose liability on one party any more than on the other, simply because some accident and injury occurred.

Thus, it can be seen that appellant connot produce sufficient evidence enabling him to rely on the doctrine of *res ipsa loquitur*. Appellant must recognize that the jury properly determined that the product was not "defective" and therefore there could have been no negligence prior to the time the product left the exclusive control of appellee. Certainly, the only other act of negligence which would be cognizable by this court would be the failure to warn, and such failure to warn can only be proven by specific evidence, since the product was not, at the time of any such alleged failure, within the control of appellee.

APPELLANT'S SPECIFICATION OF ERRORS NOS. 5, 6, 7 and 8

Appellant's specification of error No. 5 is to the effect that the trial court erred in giving an implied warranty instruction. It is difficult to perceive the thrust of his argument, since the only case cited and quoted in support thereof is the *Gottsdanker* case, which primarily abolished the doctrine of privity in imposing liability upon a manufacturer of Salk vaccine for a defective product, even though the product was "new".

Appellant then quotes from Frumer and Friedman, *Products Liability*, to the effect that the manufacturer will be an insurer if a breach of warranty is proved. As appellee has previously pointed out in this brief, no such breach can be present if there is no "defect" in the product, and Instruction No. 14, complained of in this specification, properly presented the question of breach of warranty to the jury, which decided this issue against appellant.

Appellant's assignment of error No. 6 is still another attempt to impeach the jury's verdict that there was no breach of implied warranty. Requested Instruction No. 23, which the trial court did not give, is simply a restatement of the implied warranty duty, specifically abolishing the privity requirement and substituting the term "impure" for "defect" or "not reasonably fit" and "not reasonably safe."

That appellant's argument in the specification is nothing more than the warranty argument all over again is illustrated by *Bolitho v. Safeway Stores, Inc.*, a case cited by appellant (95 P.2d 443), wherein the court cites the Montana statute (their Section 7618, Revised Code) to the effect that one who sells provisions for domestic use warrants the soundness and wholesomeness thereof and then goes on to state, at page 444:

> ". . . This statute simply enacts into statutory form what many courts hold the rule to be in the absence of statute.... (citing cases)"

Appellant's specification of error No. 7 is without merit, because there was no evidence of "overpromotion" in the instant case. Even so, the only relevance of the evidence sought would be in connection with failure to warn. It has been seen that there *was* in fact warning, notwithstanding the fact there was not even any duty to warn. The *Love v. Wolf* case was cited by appellants to show profits of a manufacturer are relevant evidence to show *motive* for overpromotion. As stated by the court at page 189:

> ". . . Proof of its sales, however, expressed either in grams or dollars, was relevant to show a motive or reason for the alleged overpromotion of the drug, a definite issue in the case...."

In the first place there was no evidence of overpromotion, as pointed out above, but equally important is the question why evidence of overpromotion itself is relevant in a case of this type. It can have no bearing on implied warranty or strict liability, for, if these doctrines are applicable, the *product* itself—without regard to extrinsic evidence—creates or negates liability. In other words, if these doctrines are applicable, then no amount of evidence of under-promotion would save the manufacturer from liability for a defective product, nor would overpromotion have any bearing thereon.

The only relevance of overpromotion is in regard to duty to warn. It is relevant to show motive for failing to warn. It is relevant to show that, if a warning were given, it was cancelled by overpromotion.

In *Love v. Wolf*, the manufacturer claimed its duty to warn was discharged as a matter of law. The court summarizes the plaintiff's counter argument thus:

> ". . . She also contends that even conceding a proper warning had been given Dr. Wolf and the rest of the medical profession, such warnings must be deemed cancelled out if overpromotion through a vigorous sales program persuaded doctors to disregard the warnings given. . . ." (p. 289)

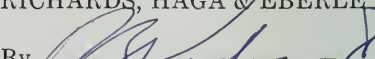
Plaintiff in the *Love* case went on to argue that a jury question was presented as to whether overpromotion cancelled out the warning given. Since proof of profits, as stated in the *Love* case, is only relevant to show a motive or reason for alleged overpromotion, it is obvious that evidence of overpromotion is a pre-

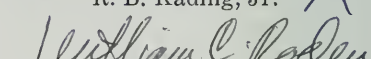
requisite to proof of any motivation to overpromote. Appellant could not and did not present adequate evidence of any overpromotion by appellee, and therefore evidence of a claimed motive for such overpromotion was irrelevant in this matter.

CONCLUSION

This case was tried before a court and jury with masses of highly technical and complex evidence presented to them. The natural sympathies for the appellant cannot override the fact that the Sabine vaccine has succeeded in effectively reducing paralytic poliomyelitis in the United States from 57,000 in 1959 (Tr. 480, line 21) to not more than 46 cases for 1965 through October. That millions of people have been insulated from this dread disease as a result of the progress of medical science is vivid testimony to the correctness of the court, in ruling upon the law, and the jury in deciding upon the sufficiency of evidence to support its verdict.

Respectfully submitted,
RICHARDS, HAGA & EBERLE

By 
R. B. Kading, Jr.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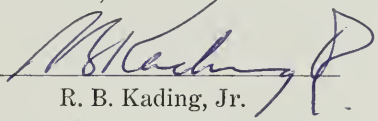
CERTIFICATE OF ATTORNEY

I certify that, in connection with the preparation of this brief, I have examined Rules 18, 19 and 39 of the United States Court of Appeals for the Ninth Circuit, and that, in my opinion, the foregoing brief is in full compliance with those rules.

RICHARDS, HAGA & EBERLE

By 

R. B. Kading, Jr.

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CERTIFICATE OF SERVICE

I hereby certify that on the 10th day of April, 1967, I personally served three copies of Appellee's brief in this matter on a member of the firm of Elam, Burke, Jeppesen & Evans, at Boise, Idaho.

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